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By: 
Printed: Matthew R. Kaser



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Sunil Shaunak et al.

Title: **COMPLEXES HAVING ADJUVANT ACTIVITY**

Serial No.: 10/585,286 Filing Date: 15th October, 2004

Examiner: PAGONAKIS, Anna Group Art Unit: 1628

Mail Stop Amendment
Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

Dear Sir:

This communication is in response to the Restriction Requirement mailed 29th January, 2010, in the above-referenced application. This response filed with a Request for a (1) one-month extension of time, thereby allowing Applicants until 29th March 2010 to respond.

Restrictions

Claims 78-97 were originally filed. In the Office Action, the Examiner stated that restriction is required under 35 U.S.C. § 121 and § 372. In addition, the Examiner stated that the inventions are not so linked as to form a single inventive concept under PCT Rule 13.1 and in accordance with 37 C.F.R. § 1.499 requested Applicant to elect claims corresponding to one of the following inventions:

- | | |
|----------|---|
| Group I | Claims 78-93, drawn to a complex comprising a narrow molecular weight distribution polymer. |
| Group II | Claims 94-97, drawn to method of treating an infection by a pathogenic organism. |

The Examiner stated that claims herein lack unity of invention under PCT Rule 13.1 and 13.2, since, under 37 CFR § 1.475(a), (w)here a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The Examiner stated that the expression "special technical features" shall mean those technical feature that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The Examiner then stated that Groups I-II lack a special technical feature as the technical feature present fails to define a contribution over the prior art. The Examiner stated that the prior art teaches of a polymeric drug obtained by polymerizing acrylic or methacrylic acid derivatives to which a physiologically active substance such as Amphotericin B (column 2, line 30; *citation not indicated by Examiner*) is bonded via an ester linkage; wherein the polymeric drug has a polydispersity of 1.1 or less, i.e. a narrow molecular weight distribution (GB 2290707 A; of record). Accordingly, the Examiner continued, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

In response to the Restriction Requirement Applicants provisionally elect Group I (claims 78-93), with traverse.

Applicants respectfully submit that the Examiner erred in stating GB 2290707 teaches the special technical features of the claims at issue. With regard to the Examiner's statement that Groups I-II lack a special technical feature as the technical feature present fails to define a contribution over the prior art, Applicants respectfully note that the prior art (GB 2290707) teaches "a polymeric drug obtained by polymerizing acrylic or methacrylic acid derivatives in which a physiologically active substance such as Amphotericin B is bonded via an ester linkage" as recited by the Examiner. The patentability of the present invention depends upon the fact that the polymer and the physiologically active substance form a complex, which is expressly not a compound containing an ester linkage: an ester linkage is a covalent linkage, whereas, as explained in the present Specification (at page 10, lines 8-15) the bonding in a complex is primarily non-covalent. The disclosure of GB 2290707 does not deprive claim 78 of novelty (because those claims are directed to a complex); neither does it deprive claim 94 of novelty, because claim 94 does not cover (nor intended to cover) the administration of a compound in which a polymer is covalently bonded to an active substance.

Applicants submit that the instant claims comprise a "special technical feature" that defines a contribution which each of the claimed inventions make over the prior art and therefore the instant claims are in compliance with 37 CFR § 1.475(a).

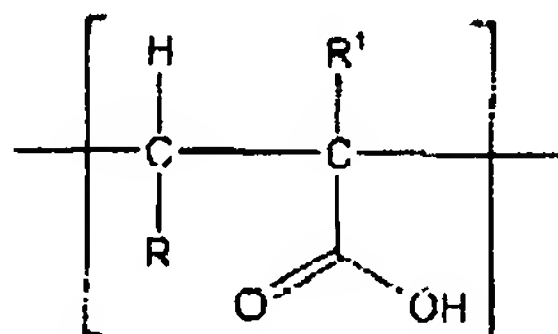
Species Election

The Examiner stated that as an additional requirement, with the election of any one of Groups I-II, an election of species of a particular species is also required.

In response to the Examiner's request, Applicants hereby provisionally elect the species of:

1) a polymer comprising

(a) unit I



(I)

;

(b) species as defined in claim 90;

(c) reads on claims 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 92, and 93;

(d) having substitutions in which R is hydrogen or methyl and R1 is hydrogen or methyl;

(e) no specific use (not applicable, as Group II not elected),

with traverse;

2) a substance that has pharmacological activity against a pathogenic organism, comprising

(a) amphotericin B;

(b) species as defined in claim 83;

(c) reads on claims 78, 79, 80, 81, 82, 83, 86, 87, 88, 89, 90, 92, and 93;

(d) no substitutions,

with traverse;

3) a substance that has pharmacological activity against a cancer, comprising

(a) daunorubicin;

(b) species as defined in the specification at page 32, line 15;

(c) reads on claims 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, and 93;

(d) no substitutions,

with traverse;

4) an antigen or immunogen, comprising

- (a) tuberculin antigen;
 - (b) species as defined in claim 84 and in the specification at page 32, line 15;
 - (c) reads on claims 78, 79, 80, 84, 86, 87, 88, 89, 90, 91, 92, and 93;
 - (d) no substitutions;
 - (e) no specific use (not applicable, as Group II not elected),
- with traverse.

Applicants respectfully submit that independent claim 78 is drawn to a genus comprising a complex comprising a narrow molecular weight distribution polymer comprising units derived from an acrylic acid or a salt thereof, and a compound selected from the group consisting of, a substance that has pharmacological activity against a pathogenic organism, a substance that has pharmacological activity against a cancer, and one or more agents selected from the group consisting of antigens and immunogens. Applicants respectfully that several exemplary species of a narrow molecular weight distribution polymer comprising units derived from an acrylic acid or a salt thereof, are disclosed throughout the specification, for example at pages 41 (unit I and unit II), 44 (unit II and unit IV), 48 (unit Ia and unit IIa), 49 (unit IIIa and unit IVa), and 61 (Scheme 3, No. 7). Therefore the Examiner erred in requesting that Applicants elect a single species of polymer for examination.

In addition, Applicants respectfully submit that the three genera recited in claims 78-93 are each members of a single Markush group. Applicants respectfully draw the Examiner's attention to MPEP 2173.05(h) that states:

Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. The materials set forth in the Markush group ordinarily must belong to a recognized physical or chemical class or to an art-recognized class; when the Markush group occurs in a claim reciting a process or a combination (not a single compound), it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is mainly responsible for their function in the claimed relationship, and it is clear from their very nature or



from the prior art that all of them possess this property.

(Applicants' emphasis)

Applicants submit the claimed polymers belong to an art-recognized class of narrow molecular weight distribution polymers, as recited in claim 78 and in the Specification at page 5, lines 2-4 and at page 8, lines 28-33 and continued on page 9, lines 1-2; furthermore, they possess at least one property in common, that property being "comprising units derived from an acrylic acid or a salt thereof" (see, for example, Specification at page 8, line 30).

Applicants further submit that the claimed substances set forth in claims 78-83 ("having pharmacological activity against a pathogenic organism"), belong to the art-recognized class of substances having pharmacological activity against a pathogenic organism (see, for example, Specification at page 30, lines 27-31 and continued on page 31, lines 1-8).

Applicants further submit that the claimed substances set forth in claim 78 ("having pharmacological activity against a cancer"), belong to the art-recognized class of substances having pharmacological activity against a cancer (see, for example, Specification at page 32, lines 9-16).

Applicants further submit that the claimed agents set forth in claims 78-83 ("an antigen or immunogen"), belong to the art-recognized class of agents of antigen and immunogens (see, for example, Specification at page 26, lines 27-32 and continued on page 27, lines 1-26).

MPEP 803 states:

If the search and examination of all the claims in an application can be made without serious burden, the examiner must examine them on the merits, even though they include claims to independent or distinct inventions.

MPEP 803.02 states:

If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they may be directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require provisional election of a single species (Applicants' emphasis).

Applicant submits that the members of the group are sufficiently few in number and are so closely related that a search and examination of the claims can be made without a serious burden and that the claims must be examined on the merits.


Applicant respectfully affirms that proper Markush language is recited in claims 78-83 and that claims 78-83 conform to MPEP § 803.02. Applicants request the Examiner reconsider the requirement for an election of a species.

The Examiner is respectfully reminded that, upon allowance of the claims to the above complex, a second process using the complex, i.e., the claims of Group II (claims 94-97), must be rejoined. See the Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)" which sets forth the rules, upon allowance of product claims, for rejoinder of process claims covering the same scope of products.

Applicants have included a petition for an extension of time of one month to respond to the Examiner's Restriction Requirement with this response. However, if the USPTO determines that an additional fee is due, the Commissioner is hereby authorized to charge Bell & Associates' Deposit Account No. 50-3194.

Respectfully submitted,

Date: 25th March 2010



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